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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,718	03/15/2001	Howard M. Johnson	UF-10164R	5517

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/808,718

Applicant(s)
Johnson et al.

Examiner
G.R. Ewoldt

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/13/02 and 2/26/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 and 6 6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group I, in Paper No. 8, filed 11/13/02, without traverse, is acknowledged.
2. Applicant's election of the species: a method comprising eliciting the expansion of antigen-specific T cells for cancer, in Paper No. 11, filed 2/26/03, with traverse, is acknowledged. Applicant traverses the implication that any generic linking claim is not allowable.

Applicant is advised that any determination as to the allowability of any linking claims cannot be established until such time as any dependent claims are found to be allowable. Given Applicant's election of species, the claims are under examination as they recite a method comprising eliciting the expansion of antigen-specific T cells for cancer treatment or prophylaxis only.

The requirement is still deemed proper and is therefore made FINAL.

3. Claim 18 is withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1-17 are being acted upon.

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because it does not include the citizenship of the Inventors.

A new declaration properly executed by all inventors is required. See MPEP §§ 608.04(b).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 9, 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) The term "SEB" is vague and indefinite as the term is not defined in the specification. Accordingly, the metes and bounds of the claim cannot be determined.

B) The phrase "whereby superantigen induced effects are exploited to advantage" in Claim 9 is vague and indefinite as the phrase metes and bounds of the method encompassed by the claim cannot be determined. Additionally, the phrase "as in" also renders the claim vague and indefinite because the claim includes elements not actually disclosed (those encompassed by "as in"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:
a method for the treatment of cancer,
does not reasonably provide enablement for:
a method for the prophylaxis (preventing), or protecting from, cancer.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

The invention of the instant claims is drawn to a method of inducing tumor antigen-specific T cells *in vivo* which respond to the specific tumor antigens of the treatment, and thus, treat or prevent cancer.

Regarding the prevention of cancer, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction"

refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (MPEP 2164.03)." The MPEP further states that physiological activity can be considered inherently unpredictable. The state of the medical art is such that no immunomodulatory methods are currently available for the prevention of cancer. Further regarding the use of the term "prevention," the term carries a connotation in the art that a disease process will not take place in a treated subject. See, for example, the most relevant definition in Webster's Collegiate Thesaurus "To stop from occurring." For these reasons, methods drawn to the prevention of cancer must be considered to require a significant amount of guidance or direction.

The specification provides insufficient data to enable claims drawn to the prevention of cancer. See, for example, Examples 1 and 2. In both instances the onset of disease is delayed, survival times are prolonged, but disease is not prevented. Given the absence of sufficient evidence in the working examples of the efficacy of the method of the instant claims, said method must be considered highly unpredictable. Given said unpredictability, the method of the instant claims must be considered to require undue experimentation.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of sufficient working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. Applicant has claimed the benefit of priority to provisional application no. 60/189,346, filed 3/14/2000, and provisional application no. 60/194,951, filed 4/01/2000. However, provisional application no. 60/189,346, was filed more than one year prior to the filing of the instant application (3/15/2000), thus, the benefit of priority to said provisional application is

denied. Accordingly, the priority date of the instant application is 4/01/2000.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-5, 7, 9, 11, and 14-17 and are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kominsky et al. (2000, IDS).

Kominsky et al. teaches a method for achieving superantigen mediated expansion of antigen-specific T cells for cancer treatment/prophylaxis which comprises administering a tumor specific antigen composition, followed by administration of a superantigen (SEA/SEB) composition at an optimized time interval (at least 4 or 7 days) following said administering of said tumor or infectious agent specific antigen composition to maximize the cellular immune response to said antigen, the cytokine response (IFN γ) to administration of said antigen, or combinations of said enhancements (see entire abstract). Note that Claim 5 is included in the rejection because V β specificities are an inherent property of superantigens. Claim 9 is included in the rejection because the method can be considered to be "exploiting" the treatment "to advantage". Claim 14 is included in the rejection because the method can be considered to enhance the activating of splenocytes (T cells). Claim 16 is included in the rejection because the method can be considered to enhance the anamnastic (secondary) response because it induces a cytokine (IFN γ). Note that the IDS indicates that the date of the reference is 4/01/2000. However, it is well-known that abstracts of presentations at scientific meetings are mailed out to all attendees of a meeting weeks before the actual date of the meeting. In the case of the meetings of The American Association for Cancer Research, the Examiner has attended and presented data at that particular meeting and can state from first-hand knowledge that the abstracts are available well in advance of the actual meeting date. Accordingly, the abstract of the rejection was "described in a printed publication", in this case over one year prior to Applicant's filing date.

The reference clearly anticipates the claimed invention.

12. Claims 1-5, 7, 9, 11, and 14-17 and are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 98/26747 (1998, IDS).

WO 98/26747 teaches a method for achieving superantigen mediated expansion of antigen-specific T cells for cancer treatment/prophylaxis which comprises administering a tumor specific antigen composition, followed by administration of a superantigen (SEA/SEB) composition at an optimized time interval following said administering of said tumor specific antigen composition to maximize the cellular immune response to said antigen (see particularly pages 18-19 and pages 6 (superantigens) and 8 (tumor antigens)). Note that Claim 5 is included in the rejection because V β specificities are an inherent property of superantigens. Claim 9 is included in the rejection because the method can be considered to be "exploiting" the treatment "to advantage". Claim 14 is included in the rejection because the method can be considered to enhance the activating of splenocytes (T cells). Claim 16 is included in the rejection because the method can be considered to enhance the anamnestic (secondary) response because it induces a cytokine (IFN γ) as this property is inherent to the claimed method.

The reference clearly anticipates the claimed invention.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kominsky et al. (2000, IDS).

Kominsky et al. (2000, IDS) has been discussed above.

The reference teaching differs from the claimed invention only in that it does not teach the use of different combinations of superantigens nor a regimen of booster vaccinations, however, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention to perform methods that comprise only routine optimization of the claimed method. Said routine optimization would fall well within the purview of one of skill in the art at the time of the invention.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 at (703) 305-3014. The CM1 Fax Center telephone numbers are 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
May 15, 2003